

June 9, 1999

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Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Re: 99P-1340/CP 1
Petition to Have "Eternity eau de parfum" Misbranded

Dear Sir or Madam:

I am a person who has had a stroke, is HIV positive, and who has multiple chemical sensitivities. Of all the barriers I encounter as a person with these disabilities, fragrance products are the most difficult. They are in use everywhere: in the hallways of the building where I live, on the buses I rely on for transportation, they are in grocery stores, banks and perhaps worst of all, in health care facilities. When I am exposed to these products I feel sick and dizzy, I can't breathe, I lose some of my mental facilities (becoming "foggy"), and sometimes I feel anger when exposed.

In May, 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded. I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 specifically states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning--The safety of this product has not been determined."

As the petition shows, "Eternity" contains toxic ingredients and

ingredients whose safety have not been substantiated. There is no warning label on its packaging.

Like tobacco smoke, the harmful chemicals currently used in these products may effect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses.

We all have a right to know the status of safety testing of the ingredients in products such as "Eternity" so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Because of this, toxic chemicals in fragrances have already ruined countless lives. They are ruining mine. Thank you.

Sincerely,

John Cailleau

**What is
“environmental illness”
and why all the fuss
about perfume?**

BY JOHN CAILLEAU

Along with ozone holes, the greenhouse effect, and other ecological calamities of the late twentieth century, we are beginning to hear a new term: "environmental illness." For some, these words may conjure up images from science fiction horror films, with bodies dying in the streets from poison gases in the atmosphere.

While air pollution does in fact sicken people all over the world, in this case environmental illness refers to individuals who cannot tolerate the quality of most indoor air and even occasional trace elements of chemicals in outdoor air.

At the same time that our society is spending billions of dollars to ensure clean outdoor air, we're buying gallons and gallons of foul-smelling chemicals to "enhance" our personal lives. Since World War II, we have been introducing an increasing number of synthetic substances into our personal environment, both at home and at work.

Canaries in a coal mine

The most sensitive among us are now reacting to this chemical overload, much as canaries died in coal mines to warn of methane gas in the early days of mining.

Exposure to perfume, even out on the street, can disable people with environmental illness for hours. Symptoms of environmental illness include mental confusion and "feeling stupid," difficulty in walking or speaking, and, in some cases, seizures, burning sinuses and eyes, and joint pain. Toxicologists believe that perfumes may produce allergic

respiratory disorders (asthma) in some people, as well as neurological and skin disorders.

Environmental illness or "multiple chemical sensitivity" (MCS) is such a disabling disease that the U.S. Social Security Administration and the Department of Housing and Urban Development are finally considering it a legitimate disability.

Perfumes are everywhere

Perfumes are increasingly used in an ever-widening variety of products, including cosmetic and hygienic products, drugs, detergents and other household products, plastics, industrial greases, oils, solvents and foods. So-called chemical enhancements take the form of plug-in room deodorizers, strong smelling laundry detergents, after-shave lotions and fabric-softening solutions designed to eliminate static cling.

In addition, the advertising and chemical industries have managed to convince many people that wearing a fragrance entitled "Joy" or "Giorgio" is preferable to smelling like a real human being. (For the consumer, the great expense of perfumes is not, for the most part, their rare ingredients, but rather their mammoth advertising and packaging budgets.)

Then there are people who spray the air with Hexol, Lysol or one of those other "clean" smelling odors rather than allowing natural smells to exist.

Open for full details on EPA Report: 1991 Study of Chemical Fragrances

Twenty Most Common Chemicals Found in Thirty-One Fragrance Products

1991 EPA Study

Reference: Lance Wallace, Environmental Protection Agency. Phone (703) 349-8970

Excerpts from "Health Hazard Information." Compiled by Julia Kendall, Co-Chair, *Citizens for a Toxic-Free Marin*. Phone (415) 485-6870

References: *Material Safety Data Sheets* (MSDS)

Principal chemicals found in scented products are—

ACETONE (in: cologne, dishwashing liquid and detergent, nail enamel remover)—On EPA, RCRA, CERCLA Hazardous Waste lists. "Inhalation can cause dryness of the mouth and throat; dizziness, nausea, uncoordination, slurred speech, drowsiness, and, in severe exposures, coma." "Acts primarily as a **central nervous system (CNS) depressant**."

BENZALDEHYDE (in: perfume, cologne, hairspray, laundry bleach, deodorants, detergent, vaseline lotion, shaving cream, shampoo, bar soap, dishwasher detergent)—**Narcotic. Sensitizer.** "Local anesthetic, **CNS depressant**" "...**irritation to the mouth, throat, eyes, skin, lungs, and GI tract causing nausea and abdominal pain.**" "**May cause kidney damage.**" "**Do not use with contact lenses.**"

BENZYL ACETATE (in: perfume, cologne, shampoo, fabric softener, stickup air freshener, dishwashing liquid and detergent, soap, hairspray, bleach, after shave, deodorants)—**Carcinogenic (linked to pancreatic cancer);** "From vapors: **irritating to eyes and respiratory passages, exciting cough.**" "In mice: hyperaemia of the lungs." "**Can be absorbed through the skin causing systemic effects.**" "**Do not flush to sewer.**"

BENZYL ALCOHOL (in: perfume, cologne, soap, shampoo, nail enamel remover, air freshener, laundry bleach and detergent, vaseline lotion, deodorants, fabric softener)—"**irritating to the upper respiratory tract**" "...**headache, nausea, vomiting, dizziness, drop in blood pressure, CNS depression, and death in severe cases due to respiratory failure.**"

CAMPHOR (in: perfume, shaving cream, nail enamel, fabric softener, dish washer detergent, nail color, stickup air freshener) "**local irritant and CNS stimulant**" "...**readily absorbed through body tissues**" "...**irritation of eyes, nose and throat**" "...**dizziness, confusion, nausea, twitching muscles and convulsions**" "**Avoid inhalation of vapors.**"

ETHANOL (in: perfume, hairspray, shampoo, fabric softener, dishwashing liquid and detergent, laundry detergent, shaving cream, soap, vaseline lotion, air fresheners, nail color and remover, paint and varnish remover)—On EPA Hazardous Waste list; symptoms: "...**fatigue; irritating to eyes and upper respiratory tract even in low concentrations.**" "...**Inhalation of ethanol vapors can have effects similar to those characteristic of ingestion.** These include an initial stimulatory effect followed by **drowsiness, impaired vision, ataxia, stupor**..." Causes CNS disorder.

ETHYL ACETATE (in: after shave, cologne, perfume, shampoo, nail color, nail enamel remover, fabric softener, dishwashing liquid)—**Narcotic. On EPA Hazardous Waste list;** "...**irritating to the eyes and respiratory tract**" "...**may cause headache and narcosis (stupor)**" "...**defatting effect on skin and may cause drying and cracking**" "...**may cause anemia with leukocytosis and damage to liver and kidneys**" "**Wash thoroughly after handling.**"

LIMONENE (in: perfume, cologne, disinfectant spray, bar soap, shaving cream, deodorants, nail color and remover, fabric softener, dishwashing liquid, air fresheners, after shave, bleach, paint and varnish remover)—**Carcinogenic.** "**Prevent its contact with skin or eyes because it is an irritant and sensitizer.**" "**Always wash thoroughly after using this material and before eating, drinking, ... applying cosmetics. Do not inhale limonene vapor.**"

LINALOOL (in: perfume, cologne, bar soap, shampoo, hand lotion, nail enamel remover, hairspray, laundry detergent, dishwashing liquid, vaseline lotion, air fresheners, bleach powder, fabric softener, shaving cream, after shave, solid deodorant)—**Narcotic** "...**respiratory disturbances**" "Attracts bees." "In animal tests: ataxic gait, reduced spontaneous motor activity and depression ... development of respiratory disturbances leading to death." "...**depressed frog-heart activity.**" Causes CNS disorder.

METHYLENE CHLORIDE (in: shampoo, cologne, paint and varnish remover)—**Banned by the FDA in 1988! No enforcement possible due to trade secret laws protecting chemical fragrance industry.** On EPA, RCRA, CERCLA Hazardous Waste lists. "**Carcinogenic**" "...**Absorbed, stored in body fat, it metabolizes to carbon monoxide, reducing oxygen-carrying capacity of the blood.**" "**Headache, giddiness, stupor, irritability, fatigue, tingling in the limbs.**" Causes CNS disorder.

a-PINENE (in: bar and liquid soap, cologne, perfume, shaving cream, deodorants, dishwashing liquid, air freshener)—**Sensitizer (damaging to the immune system).**

g-TERPINENE (in: cologne, perfume, soap, shaving cream, deodorant, air freshener)—"**Causes asthma and CNS disorders.**"

a-TERPINEOL (in: perfume, cologne, laundry detergent, bleach powder, laundry bleach, fabric softener, stickup air freshener, vaseline lotion, cologne, soap, hairspray, after shave, roll-on deodorant)..." **highly irritating to mucous membranes**" "...**Aspiration into the lungs can produce pneumonitis or even fatal edema.**" Can also cause "**excitement, ataxia (loss of muscular coordination), hypothermia, CNS and respiratory depression, and headache.**" "**Prevent repeated or prolonged skin contact.**"

Unable to secure MSDS for the following chemicals:

1,8-CINEOLE; b-CITRONELLOL; b-MYRCENE; NEROL; OCIMENE; b-PHENETHYL ALCOHOL; a-TERPINOLENE

- 95% of chemicals used in fragrances are synthetic compounds derived from petroleum. They include **benzene derivatives, aldehydes** and many other known toxics and sensitizers—capable of causing cancer, birth defects, central nervous system disorders and allergic reactions. *Neurotoxins: At Home and the Workplace, Report by the Committee on Science & Technology, U.S. House of Representatives, Sept. 16 1986. (Report 99-827)*
- Central Nervous System disorders (brain and spine) include Multiple Sclerosis, Parkinson's Disease, Alzheimer's Disease, Sudden Infant Death Syndrome.
- **Chloroform** was found in tests of fabric softeners: *EPA's 1991 study.*
- A room containing an air freshener had high levels of **p-dichlorobenzene** (a carcinogen) and **ethanol**: *EPA's 1991 study.*

- An FDA analysis (1968-1972) of **138** compounds used in cosmetics that most **frequently involved adverse reactions**, identified five chemicals (**alpha-terpineol, benzyl acetate, benzyl alcohol, limonene and linalool**) that are among the 20 most commonly used in the 31 fragrance products tested by the EPA in 1991!
- Thirty-three million Americans suffer from sinusitis (inflammation or infection of sinus passages).
- Ten million Americans have asthma. Asthma and asthma deaths have increased over 30% in the past 10 years.
- Headaches cost \$50 billion in lost productivity and medical expenses and 157 million lost work days in 1991. "Focus on Fragrance and Health," by Louise Kosta, *The Human Ecologist*, Fall 1992.

5,000 Ingredients

The adverse reactions of people with environmental illness to this chemical bombardment is not surprising when one considers the list of ingredients in most popular and well-advertised perfumes. According to the French toxicology journal, *Ann Demeristol Venereol*, the composition of perfumes is usually complex, involving "numerous natural and synthetic sweet-smelling constituents, more than 5,000 of which are known."

Some 95 percent of chemicals used in fragrances are synthetic compounds derived from petroleum. according to a 1986 report, *Neurotoxins: At Home and the Workplace*, by the U.S. House Committee on Science and Technology.

Ingredients such as benzene derivatives, aldehydes, and other known toxins and sensitizers are "capable of causing cancer, birth defects, central nervous system disorders and allergic reactions," the report stated.

And the vast majority of the ingredients in perfumes "have never been tested for human toxicity, or have been tested only minimally," wrote N. Ashford Ph.D. and C. Miller, M.D. in their 1991 article *Chemical Exposures: Low Levels, High Stakes*.

Unfortunately, many people with environmental illness are so ill that even exposure to so-called natural oils and fragrances produce the same symptoms as synthetic perfumes.